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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,333	01/09/2001	Samuel I. Achilefu	MRD-67	5506

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,333	ACHILEFU ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/6/04; 2/23/04; 5/20/04; and 7/22/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04 & 7/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the acceptable RCE filed 5/20/04. In addition, the amendment filed 2/6/04 wherein claims 1, 2, 4, 5, 16, 18, and 19 were amended.

Notes: (1) Claims 1-20 are pending.

(2) The amendment filed 2/23/04 is a duplicate of the amendment filed 2/6/04.

NEW GROUNDS OF REJECTIONS

Double Patenting Rejections

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-11 and 18-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 15 of U.S. Patent No. 6,733,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds, compositions, and uses thereof wherein compounds as set forth in independent claims 1, 4, and 18 (instant invention). The claims differ in that the structured of the instant invention is not exactly the same as that of the patented invention. However, when a3 = 1; b3 = 1; and W3 and X3 are CR1R1 (09/757,332), species of the instant invention are encompassed.

4. Claims 4-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-17 of copending Application No. 09/757,332. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds, compositions, and uses thereof wherein compounds as set forth in independent claims 1, 4, and 18 (instant invention). The claims differ in that the structured of the instant invention is not exactly the same as that of 09/757,332. However, when a5 = 1; b5 = 1; and W5 and X5 are CRcRd (patented invention), species of the instant invention are encompassed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 4-6, 8, 9, 11, and 13-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39, 40, 43, and 44 of copending Application No. 10/800,531. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed inhibiting fluorescence quenching in a photodiagnostic or phototherapeutic process wherein an organic solvent is administered in combination with a compound of independent claim 4 (instant invention). The claims differ in that claim 4 of the instant invention does not specifically state that an organic solvent that inhibits quenching is present. However, dependent claims 16 and 17 of the instant invention are directed to quenching inhibitors. ***Note***: in the formula of 10/800,531, a3 = 1; b3 = 1; and W3 and X3 = CR1R2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 4-6, 8, 9, 11, 13, and 14-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39, 40, 43, and 44 of copending Application No. 10/802,112. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed inhibiting fluorescence quenching in a

photodiagnostic or phototherapeutic process wherein an organic solvent is administered in combination with a compound of independent claim 4 (instant invention). The claims differ in that claim 4 of the instant invention does not specifically state that an organic solvent that inhibits quenching is present. However, dependent claims 16 and 17 of the instant invention are directed to quenching inhibitors. ***Note***: in the formula of 10/802,112, a3 = 1; b3 = 1; and W3 and X3 = CR1R2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 Rejections (First Paragraph)

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for the preventing in vivo or in vitro fluorescence quenching. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue

experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the instant invention is directed to a method of preventing the in vivo or in vitro fluorescence quenching using an organic solvent as set forth in dependent claim 16. A skilled practitioner in the art would be *motivated* to use an organic solvent to inhibit quenching. However, preventing quenching is not guaranteed since (1) reduction of quenching indicates that quenching is occurring, but not prevented; and (2) prevention of quenching indicates that no quenching may occur. In other words, prevention of quenching means that fluorescence from administering the subject the compound/composition *never* experiences any characteristics associated with decreased fluorescence. Hence, the amount of guidance present in the specification, the absence of data indicating that the compounds when in the presence of an organic solvent never experience quenching and the state of the prior art, all indicate that *inhibition of quenching, not prevention of quenching* is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amount of the compound in combination with various organic solvents to determine which combination prevents fluorescence quenching. Hence, the

amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate combination of organic solvent and compounds encompassed by the formula of independent claim 4.

112 Rejections (Second Paragraphs)

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7 and 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4, 5, 18, and 19: The claims as written are ambiguous because the variable B3 is not connected to the two single double bonds in the ring containing A3, B3, C3, and D3, but attached to the outside of the two single bonds. Thus, B3 is outside the ringed structure. In addition some of the subscripts are difficult to read (i.e., the variable 'a'). Hence, Applicant is respectfully requested to correct the structure in regards to the location of B3 and make sure all variables are readable.

Claims 4-7 and 10-17: The claims as written are ambiguous because it is unclear what diagnostic or therapeutic procedure is being performed. Please clarify in order that one may readily ascertain what procedure(s) is/are being claimed.

Claim 13: The claim is confusing because it is unclear what localized therapy Applicant is referring to since it depends upon claim 4 which itself is directed to therapy. Please clarify.

Claims 2, 3, 5, 6, 19, and 20: The claims are confusing because W5 and X5 = C((CH2)OH)2 and C((CH2)aCO2H)2 have been deleted from their respective independent claims, but is listed in the dependent claims. Please correct for consistency throughout the claims.

Claims 2 and 5: W5 and X5 = X((CH2)OH)CH3, C((CH2)aNH2)CH3, C(CH2)a(NH2)2, and [C(CH2)aNR3R4]2 are not encompassed in Applicant's definitions of W5 andX5 in their respective independent claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

August 19, 2004